

REMARKS

Reconsideration of this application is requested.

Non-elected claim 14 has been deleted without prejudice to divisional filing.

Reconsideration of the Section 112, 1st paragraph rejection of claims 1-9, as set out in Section 5 of the action, is respectfully requested, particularly in view of the amendments made to claim 1. It is noted that the Examiner accepts that the applicants' disclosure is enabling for the treatment of diarrhoea but questions the adequacy of the enablement with respect to the prevention of diarrhoea. While the applicants do not agree with the Examiner's position, claim 1 has been amended to specify the prevention of diarrhoea in young mammals normally subject to diarrhoea, notably weaning mammals as specified in new claim 16 and more specifically in amended claim 2. It is respectfully submitted that the claims, as amended, are fully enabled by the disclosure. The applicants' disclosure clearly teaches that the invention is useful in the prevention of diarrhoea in young mammals and Example 1 shows how the invention is used to prevent diarrhoea in weaning piglets. The Examiner has given no reason why one skilled in the art could not use the invention for prevention of diarrhoea as claimed. It is believed that the Examiner's requirement that the applicants demonstrate prevention under each and every condition causing diarrhoea goes beyond the statutory requirements for enablement. The key issue is whether or not one skilled in the art could use the invention as claimed to prevent diarrhoea in young mammals normally subject to diarrhoea without undue experimentation. The applicants respectfully submit that their disclosure meets this test. Accordingly, withdrawal of the enablement rejection is requested.

The Examiner is also requested to reconsider the Section 112, 2nd paragraph rejection of claims 1-9, 12 and 13 in view of the amendments which have been made in claims 1, 2, 3, 5 and 12. Thus, the parentheses have been deleted from claim 1 and the reference to "babies" in claim 2 has been qualified to "weaning babies". Support for this amendment is evident from the specification at, for example, page 2, lines 4-7 and line 14.

Claims 3, 12 and 5 have also been amended to deal with the formal points raised by the Examiner in Sections 8 and 9 of the action.

New claims 15 and 16 have been presented for consideration. Claim 15 specifies that the diarrhoea is caused by bacterial infection following the Examiner's acknowledgement as to applicants' support for this feature on page 3, 2nd full paragraph of the action. Basis for this claim is found throughout the applicants' disclosure. See, for example, page 2, lines 1-2.

New claim 16 is modeled after claim 2 but somewhat more broadly defines the subject mammals as weaning mammals. See, for example, the paragraph bridging pages 1-2 of the applicants' specification for support.

Claims 15 and 16 are thought to be in acceptable form and otherwise allowable for the same reasons as noted herein with respect to claims 1-9.

Reconsideration of the Section 102(b) rejection of claims 10-12 based on U.S. Patent 6,149,961 ('961) is requested, particularly in view of the amendments which have been made in claim 10, basis for which is found at, for example, page 4, 1st full paragraph of applicants' specification. The amendments to claim 10 are believed to distinguish the applicants' animal feed from anything disclosed by '961, expressly or inherently. Clearly the reference does not in any way disclose applicants' method of preparing an animal feed having anti-diarrhoea or anti-scouring properties by incorporating in the animal feed an amount of the active component specified in claim 10 effective to obtain the desired anti-diarrhoea or anti-scouring properties.

The applicants do not consider that the Examiner can properly reject claims 10-12 as anticipated by the reference on any inherency basis, particularly in view of the amendments to claim 10. Hence withdrawal of the Section 102(b) rejection based on '961 is requested.

It is noted that the Examiner has not applied '961 under Section 103(a). This is understandable as there is nothing suggestive of the applicants' invention in '961. Thus, the applicants' claims 10-12 are concerned with methods of preparing an animal feed that exhibits anti-diarrhoea or anti-scouring properties while '961 (U.S. '961), in contrast, discloses a fat-substitute comprising a plasticized Shea nut extract. The '961 is only concerned with the provision of healthier prepared food products in which part or all of the fat in prepared food products is replaced by the fat substitute of the invention. In this way, the total amount of fat and/or calories in the resulting food product is reduced. There is no disclosure, mention or suggestion in '961 that the fat substitute could be incorporated into an animal feed, let alone that it would exhibit anti-diarrhoea properties.

It is, of course, well known that the requirements for an animal feed are very different from those of food products for humans, particularly low fat and/or low calorie products. Accordingly, there would be no reason for a person skilled in the art of formulating animal feed to consult '961.

The Examiner is also requested to reconsider the Section 103(a) rejection of claims 1-13 as unpatentable over WO 02/056879 (WO '879) in view of WO 02/055087 (WO '087). These references do not make the applicants' invention of claims 1-13 obvious. There is, for example, no motivation in the art to combine the reference disclosures as the Examiner has suggested in the rejection of the claims. Clearly there is no suggestion in either reference to the effect that the triterpene compositions of WO '087 could be effectively used as a replacement for the actives used in WO '879. Furthermore, even if the references are combined on the basis of hindsight in the light of the applicants' disclosure, the applicants' invention does not result.

More specifically, WO '879 teaches that diarrhoea is caused by a bacterial infection and is treatable with antibiotics. The compositions disclosed in WO '879, however, do not comprise phytosterols or pentacyclotriterpenes as in the present invention. The compositions of WO '897 contain terpenes such as carvone and geraniol (see claim 2). This is not in any sense suggestive of the applicants' invention.

WO '087, on the other hand, describes dietary, pharmaceutical and cosmetic compositions, and methods of preparation thereof. The compositions of WO '087 comprise a dihydro-triterpene and, in the examples, were obtained by hydrogenation. There is no disclosure in WO '087 that the compositions may comprise sterols, as in the present invention.

As stated in WO '087 at page 3, lines 38 and 39, triterpenes are known to exhibit numerous pharmaceutical effects. However, such effects are highly diverse and depend on the specific structures of the triterpenes. In view of this, and the fact that WO '087 only teaches the pharmaceutical effects exhibited by certain dihydro-triterpenes, it would not have been obvious to the skilled person that compositions comprising the applicants' chemically different pentacyclotriterpenes and sterols, as in the present invention, would exhibit any pharmaceutical activity, let alone be useful in the treatment and prevention of diarrhoea in mammals.

The applicants also submit, for the reasons noted, that it would not have been obvious for the skilled person to combine the teachings of WO '879 and WO '087.

Clearly, as noted above, there is no art motivation to do so. WO '087 relates to compositions that exhibit anti-inflammatory and antiviral effects while WO '879 teaches that diarrhoea is caused by bacterial infections. The skilled person would not have thought it obvious to combine the teaching of WO '879 and WO '087, in view of the fact that the compositions of WO '087 do not concern the treatment of bacterial infections. Furthermore, even if the skilled person had combined the teaching of WO '879 and WO '087 (which the applicants do not accept), the skilled person still would not have arrived at the presently claimed invention in view of the different actives involved.

The foregoing comments are primarily directed towards distinguishing applicants' method claims 1-9 and new claims 15 and 16 from the Examiner's WO references. However, it is also noted that these references are in no way suggestive of the applicants' methods of preparing an animal feed as defined by claims 10-13. These claims require that the active components are phytosterols and/or pentacyclotriterpenes. WO '087, in contrast, discloses pharmaceutical compositions and dietary supplements comprising dihydro-triterpenes. A definition of dietary supplement is provided at page 9, lines 30 to 38 and page 10, lines 1 to 6, where it is defined as a product that "is intended for ingestion in pill, capsule, tablet, or liquid form". In contrast to the present invention, there is no disclosure, mention or suggestion in either of the documents that the active components could be incorporated into an animal feed.

Furthermore, the compositions of WO '087 preferably relate to formulations that are for topical or transdermal administration (see page 9, line 26). It would, therefore, not have been obvious, or even contemplated, by the skilled person, in view of the teaching of WO '087, that the active components of the present invention would remain therapeutically effective incorporated into, and made part of, an animal feed. WO '087 describes the use of a pharmaceutical carrier which enhances therapeutic activity (see page 5, lines 15 to 17 of WO '087). In view of this, the skilled person would not have attempted, or even considered, incorporating the active components into a food product, as in the present invention. The skilled person would not have thought this to be an effective form of administration of the active components.

For all of the above reasons, it is submitted that the applicants' claims satisfy the requirements of Section 112 and define subject matter which is both new and unobvious

from the prior art relied on by the Examiner. Accordingly, favorable reconsideration, with allowance, is requested. The Examiner is encouraged to telephone the undersigned if there remain any issues which need to be resolved for allowance.

Respectfully submitted,

MORGAN LEWIS & BOCKIUS LLP

By 

Paul N. Kokulis
Reg. No. 16773

Date: June 28, 2005

Customer No. 09629

1111 Pennsylvania Avenue, N.W.

Washington, D.C. 20004

Phone: (202) 739-3000

Facsimile: (202) 739-3001

Direct: (202) 739-5455